DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Pfizer Consumer Healthcare
Pfizer Inc.
Attention: Robert Kohler
Regulatory Affairs
201 Tabor Road
Morris Plains, New Jersey 07950

APR 15 2002

RE: Docket No. 98N-0337
Application for Exemption
APP 40

Dear Mr. Kohler:

We are responding to your application for exemption (APP) 40, dated February 27, 2002, requesting a deferral of the compliance time for implementation of the Drug Facts labeling requirements in 21 CFR 201.66(c) and (d) for Rolaids® 10-count (Regular) roll and 12-count (Extra Strength) roll.

You mentioned the limited amount of space that is available for labeling on these shelf-keeping units. You requested a deferral of 7 months beyond the May 16, 2002, compliance date to implement a new roll package label for these products. You stated that your company needs this deferral to acquire, install, and validate the equipment necessary to produce a compliant roll label on a reliable, repetitive basis. You indicated that the label and equipment are innovative technologies that require sufficient development time to master the interface between equipment and material. You provided a projected timeline for implementation of the label.

Your deferral request indicated that the company would start to ship new product in the 4th quarter of 2002. For the reasons provided in your application, the agency is, as a matter of enforcement discretion, granting your company's request for a deferral from the "Drug Facts" labeling requirements in 21 CFR 201.66. We intend to exercise enforcement discretion for the products identified in APP 40 for a period of 7 months after May 16, 2002. At the end of this deferral period (i.e., December 16, 2002), the labeling for these products must comply with the requirements of 21 CFR 201.66 at the time the products are initially introduced or initially delivered for introduction into interstate commerce.

If you have any comments or questions regarding this deferral, please reference the docket and application for exemption numbers and submit them to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. I hope this information is helpful.

Sincerely yours,

Charles J. Ganley, M.D.
Director
Division of OTC Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research